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PRINCIPAL INVESTIGATOR:
Ashok Tuteja, M.D. M.P.H.

CONTRACTING ORGANIZATION:

Western Institute For Biomedical Research
Salt Lake City, UT 84148

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14. ABSTRACT

The overall objective of the study was to determine whether Bifidobacterium infantis 35624 (Align®) will improve symptoms of GW illness.

We have not started the study as yet. We were unable to get IND (Investigational New Drug) number for the probiotic, Bifidobacterium infantis 35624 (Align®). We requested the Department of Defense to allow us to use another commonly used probiotic, VSL#3. The Department of Defense contract has been modified to include this change. The Confidentiality Disclosure Agreement between VSL Pharmaceuticals and the Department of Veterans Affairs has been agreed. We have received IND from the Food and Drug Administration (FDA) for VSL#3. Our application is with University of Utah Institutional Review Board at the final stages of approval. This application will be sent to Department of Defense for their approval before starting the study.

15. SUBJECT TERMS

Irritable bowel syndrome, probiotic, Gulf War Illness, diarrhea

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Introduction:

Gastroenteritis during deployment is a risk factor for the development of irritable bowel syndrome (IBS) after deployment. Gulf War Veterans with IBS are more likely to report fatigue, joint pain, general stiffness and headache- common clinical features of GW Illness. Gastroenteritis plays a major role in changing the gut microflora. Gut microflora are also known to change with travel, stress and diet changes- factors which are relevant to GW Veterans. Altered gut flora may be the etiological factor for IBS and GW Illness. Probiotics are living organisms that improve health by re-establishing a normal gut flora.

The overall objective of the study was to determine whether Bifidobacterium infantis 35624 (Align®) will improve symptoms of GW illness. We will study patients who have GW illness or chronic multi-symptom illness and IBS.

We have not started the study as yet. This was due to inability to get IND (Investigational New Drug) number for the probiotic, Bifidobacterium infantis 35624 (Align®). The manufactures of Bifidobacterium infantis 35624 (Align®), Procter & Gamble could not provide the necessary manufacturing information to Food and Drug Administration (FDA). We requested the Department of Defense to give us permission to use another commonly used probiotic, VSL#3. The Department of Defense contract has been modified to include this change. The FDA has given us the IND to study VSL#3. Our application is under review with the University of Utah Institutional Review Board (IRB) for approval.

Body

Thus far we have created informed consent form and formatted the surveys to evaluate IBS, dyspepsia, post traumatic stress disorder (PTSD) and fatigue for administration before, during and after treatment with the probiotic. We submitted these documents to the University of Utah IRB. The IRB determined that we needed to obtain either an Investigational New Drug IND application or a waiver for an IND from the FDA.

We submitted the request for IND to the FDA. The FDA informed us to withdraw the application because more manufacturing data was required from the Proctor & Gamble.

We re-submitted the application to the FDA along with the expanded protocol to meet the requirements of the FDA and necessary manufacturing information of the probiotic. However, the FDA required detailed manufacturing information from P&G.

We have also been in contact with the University of California, Berkeley IRB. We have submitted a protocol summary for their approval. They approved of our protocol and pending University of Utah IRB approval, we will immediately gain University of California, Berkeley IRB approval.

We continued to have problems in procuring the required manufacturing information from the distributors of the probiotic, Align® (Bifidobacterium infantis 35624). We therefore requested the Department of Defense to give us permission to use a different commonly used probiotic, VSL#3. We received the new contract in September 2011.

The distributors and manufactures of VSL#3 have helped several investigators obtain an IND and have agreed to support our protocol. The Confidential Disclosure Agreement and the contract between VSL Pharmaceuticals Inc and the Department of Veterans Affairs was completed. We all these documents we applied to the FDA for IND. We have been granted IND to study VSL#3 for Gulf War Illness.

Key Research Accomplishments

Manuscripts:

1. Tuteja, AK. Deployment associated functional gastrointestinal disorders: do we know the etiology? Dig Dis Sci 2011: 56(11):3109-11.

2. Tuteja AK, Fang JC, Al-Suqi M, Stoddard GJ, Hale, D. Double-blind Placebo Controlled Study of Mesalamine in Post-infectious IBS. Scandinavian Journal of Gastroenterology, 2012;47(10):1159-64).

Abstracts:

1) Tuteja AK, Piceno YM., Talley NJ, Andersen, GL. Changes in Fecal Microbiota of Gulf War Veterans with Irritable Bowel Syndrome, Gastroenterology 2010, suppl

2) Tuteja AK, Grandemange A, Waddoups L, Stoddard GJ, Tolman KG, Lipman AG. Effect of Methylnaltrexone on Anorectal Function in Patients with Opioid-induced Constipation. Am J Gastroenterol 2011 (Suppl)

3) Tuteja AK, Talley NJ, Samore, M, Stoddard G, Verne NG. Prevalence and risk factors for fecal incontinence in male gulf war veterans. Neurogastroenterology and Motility 2012; September (Suppl)

4) Iles-Shia L, Go M, Hatton-Ward S. Tuteja AK. Clinical Utility of Anorectal Manometry in Fecal Incontinence and Chronic Constipation in Men. Am J Gastroenterol 2012 (Suppl)

Reportable Outcomes

Nil

Conclusion

We are in the process of starting the project. Our application should get approval from the University of Utah IRB within this month. After this we will send this application to the Department of Defense for their IRB approval prior to starting the study.

We should be starting this study during the early part of 2013.

References

Nil

Appendices

Nil